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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,864	06/23/2005	Frederick L. Coe	80337.0018 US	2996
41913	7590	11/15/2006	EXAMINER	
HOGAN & HARTSON L.L.P., 875 THIRD AVENUE NEW YORK, NY 10022			HOPKINS, CHRISTINE D	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/524,864

Applicant(s)

COE, FREDERICK L.

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>14 Feb 2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claim 1 at line 7 and claim 22 at line 5 are objected to because of the following informalities: "inflation" should read --inflatable--. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 at line 2 recites "wherein said outlet is the peritoneal cavity of the patient." The positive recitation of a part of the human body renders the claim non-statutory. Claim 9 renders the limitation at line 10 of claim 1 a positive recitation of the living body.

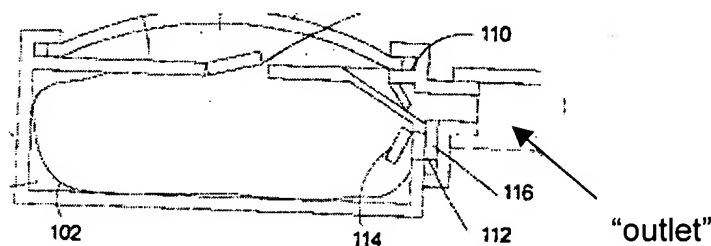
Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 6 and 9-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Meah (U.S. Patent No. 6,432,040). Meah discloses an implantable sphincter capable of surround the stomach of a patient. Regarding claims 1 and 22-24, Meah teaches an adjustable band to be placed over the first part of the stomach adjoining the esophagus. The band has an internal inflation chamber to be increased or decreased thereby adjusting the tightness of the device (col. 2, lines 15-21). The inflation device has a fluid reservoir for providing fluid to the inflatable chamber (col. 2, lines 47-50). A first valve **110** is between the fluid reservoir **102** and the inflatable chamber of the band (sphincter body comprising the adjustable band) for expanding the sphincter body (col. 6, lines 4-15 and Fig. 6). A second valve **114** is between the inflatable chamber and an "outlet" (see depiction below).



A "controller," or diaphragm **96** actuates the valves, thereby increasing or decreasing the amount of fluid introduced into the sphincter body for adjusting its opening and thus imposing a tighter fit on the organ. The "controller" **96** is remotely controllable from outside the patient since the patient can physically press on the "controller" located under the skin of the patient (col. 6, lines 9-15). In view of claim 2, the "remote control" is construed as the action of the patient pressing on the "controller" **96** located internal

to the patient. Regarding claim 3, the “receiver” is construed as valve **106** since it receives control signals from the patient pressing the “controller” **96**. The “controller” **96** in turn, actuates valves **110** and **114** in response to the deflection of the diaphragm, or “controller” **96** by patient’s external manipulation (col. 6, lines 5-15).

With reference to claims 4 and 6, Meah further teaches a power source for providing power to the controller in the form of a battery (col. 5, lines 41-44).

Regarding claim 10, the “outlet” as construed in claim 1, is also considered to be a “waste reservoir” since no further structure is provided in the claim language. In view of claim 11, since the fluid flows from an area of high pressure in the fluid reservoir **102** through valve **114** to the “outlet” (refer back to depiction above), the “waste reservoir,” which constitutes the “outlet,” is considered to be “negatively pressurized.”

With respect to claims 12-14, the inflatable chamber **28** is coextensive with an inner stomach-facing surface **30** (col. 4, lines 20-22 and Fig. 3). The inflatable chamber **28** does not fold or wrinkle as a result of its inextensible outer surface **62**, rendering the inner surface substantially smooth (col. 4, lines 52-60 and Fig. 3).

Regarding claim 15, the band of Meah may further incorporate a filament **54** having teeth along one side for locking with receptacle **56** (col. 4, lines 41-46). In view of claim 16, the fluid that fills the sphincter body is a saline solution (col. 5, lines 21-23).

With reference to claims 17-19, Meah teaches an adjustable band, having an inflatable member, being placed around the first part of the stomach adjoining the esophagus (col. 2, lines 15-21), thus defining a treatment method for obesity. Meah further discloses a “remote control,” or an external control device **84**, that transmits

instructions to a "controller" **74**, having a receiver **82**, inside the patient for controlling the movement of fluid into or out of the banding device (col. 5, lines 39-47). The receiver-controller actuates a "first valve," or bi-directional pump **76** located between fluid reservoir **80** and tube **24** leading to the inflatable chamber of the sphincter body to move fluid into or out of it, consequently adjusting the inner circumference of the band (col. 5, lines 41-47).

Regarding claims 20 and 21, Meah teaches that the inflatable chamber **28** is coextensive with an inner stomach-facing surface **30** (col. 4, lines 20-22 and Fig. 3). The inflatable chamber **28** does not fold or wrinkle as a result of its inextensible outer surface **62**, rendering the inner surface substantially smooth (col. 4, lines 52-60 and Fig. 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meah (U.S. Patent No. 6,432,040) in view of Dargent et al. (U.S. Patent No. 6,547,801). Meah discloses the invention as claimed, see rejection supra; however Meah fails to disclose the type of power source utilized. Dargent et al. (hereinafter Dargent) teach a constriction device for treating morbid obesity. Regarding claims 5 and 7, Dargent

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teaches an induction coil **36** located within the receiver **11** and connected to an electrolytic capacitor **39** to store, charge and provide power for the receiver to actuate and drive the motor **21** (col. 8, lines 17-33), which in turn, determines the degree of constriction of the device (col. 7, lines 37-40). Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to have employed an induction coil and a capacitor as taught by Dargent to power the constriction device of Meah that adjusts the degree of constriction on the stomach.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meah (U.S. Patent No. 6,432,040) in view of Dargent et al. (U.S. Patent No. 6,547,801) and further in view of Laub (U.S. Patent No. 5,944,751). The combination of Meah and Dargent disclose the use of a capacitor as a power source, see rejection supra; however, the combination fails to teach that the capacitor is piezo-electrically charged. Laub discloses an implantable, electromechanical valve controlled by a power supply. Regarding claim 8, Laub teaches that the energy generated by movement of the valves supplies a small current through piezoelectric means to power an oscillator. Therefore, at the time of the invention, it would have been obvious to one having ordinary skill in the art to have supplied a capacitor as taught by the combination of Meah and Dargent with piezoelectric means for charging a capacitor as disclosed by Laub for generating charge to power an implantable device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,928,195 to Malamud et al. discloses a remotely controlled drug delivery device that may be used in any body cavity.

U.S. Patent No. 5,938,669 to Klaiber et al. discloses an adjustable gastric banding device used for the treatment of obesity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christine D Hopkins
Examiner
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